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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
087819,669	03/17/97	BOON	T LUD-5253.5-D

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HM11/0901

EXAMINER  
CUNNINGHAM, T

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/01/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/819,669**

Applicant(s)  
**Boon et al.**

Examiner  
**Thomas Cunningham**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Jul 9, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 173-181 is/are pending in the application.

Of the above, claim(s) 177 and 178 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 173-176 and 179-181 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 173-181 are pending. The amendment filed under 37 C.F.R. 1.111 mailed 6/9/98 has been entered as Paper No. 10.

2. Applicant's prior election without traverse of Group I, claims 173-177 as directed to the MAGE-1 tumor rejection antigen precursor encoded by SEQ ID NO: 8 in Paper No. 8 is acknowledged. Applicant has indicated that claims 173 and 174 are generic, that claim 177 is subgeneric and that claim 175 is drawn to MAGE-1.

Claims 179-181 added by preliminary amendment are directed to compositions of matter encompassing the isolated tumor rejection antigen precursor of claim 173. These are considered part of the elected invention and will be examined to the extent that they encompass MAGE-1 (SEQ ID NO: 8).

Claims 177-178 and the generic and subgeneric claims as they read on nonelected proteins have been previously withdrawn from consideration.

3. The Examiner appreciates the Applicant's thoroughness in amending the specification to recite series numbers. A complete application number must include both a series number, such as "08/" and a serial number. Though a minor procedural detail, omission of a series number may result in delay of issuance of a patent, as Drafting Division will remand such an application to the Examiner for correction.

4. Claims 179-181 are rejected under 35 U.S.C. 112, second paragraph as failing to particularly point and distinctly claim the invention.

A. (Maintained) It is unclear what the metes and bounds of the term "composition" are. Is this limited to noncovalently associated ingredients, such as an isolated MAGE-1 antigen and an excipient such as PBS or normal saline? Is this term intended to embrace fusion proteins or protein conjugates comprising the MAGE-1 antigen, e.g. MAGE-1 conjugated to a protein carrier such as KLH or diphtheria toxoid? Is the term "composition of matter" intended to have a different scope or meaning than the term "composition" as conventionally used in biotechnology claim language?

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--Applicant has amended the claims to change "composition of matter" to "composition". It is unclear from the Applicant's response whether the term "composition" is limited to noncovalently-associated ingredients.

B. (Withdrawn) It is unclear what the metes and bounds of the term "isolated" are. It is presumed that this encompasses MAGE-1 which is isolated from other antigens or tissue components which it is ordinarily associated, e.g. other tumor cell proteins or products. Does this term also require that the isolated MAGE-1 antigen not be covalently attached to another component, such as a carrier protein or effector component?

--This rejection is withdrawn because the Applicant indicates that this term limits the claimed component to the TRAP per se. Thus, this term excludes an isolated TRAP that is covalently-conjugated to another component.

C. (Withdrawn) In claims like claim 173-175 and 179-181, it is unclear what the metes and bounds of the claimed isolated tumor rejection antigen are. For instance, is the MAGE-1 protein of claim 175 limited to the full-length translate of SEQ ID NO: 8, or does it also encompass fragments encoded by a portion of SEQ ID NO:8? If SEQ ID NO: 8 is genomic DNA, then is the recited MAGE-1 protein limited to amino acid residues encoded by the MAGE-1 exons?

D. (Withdrawn) In claim 173 it is unclear whether the term "non tum-antigen" refers to a non-tum<sup>-</sup> (minus) antigen. Is the dash "-" intended to be a superscript minus sign? See e.g. page 3 of the specification which refers to tum<sup>+</sup> and tum<sup>-</sup> antigens. Alternatively, does this hyphenated term refer to any non-tum antigen, whether a tum<sup>+</sup> and tum<sup>-</sup> antigen?

5 (Withdrawn) The prior rejection of claim 176 under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed tumor rejection antigen, MAGE-1 is withdrawn in view of the Applicant's comments on page 4 of the last response.

6. (Withdrawn) The prior rejection of claim 181 under 35 U.S.C. 112, fourth paragraph as failing to further limit the ingredients of the claimed composition is withdrawn in view of the Applicant's comments which indicate that not all pharmaceutically appropriate ingredients are necessarily "in the form of a vaccine".

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7. The amendment filed 7/9/98 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

A. Correction of the nucleotide sequence of SEQ ID NO:7.

B. Correction of the nucleotide sequence of SEQ ID NO:8.

The declaration filed 7/9/98 has been considered and indicates that the correction is permissible because the Applicant's originally had possession of the original clone which inherently had the correct sequence for MAGE-1, and that the sequence error was attributable to sequencing error due to band compression. Applicant's declaration indicates the error was discovered and corrected in the Genbank database in 1993 prior to filing of the instant application. The instant claims under examination are described in terms of proteins encoded by the sequence of SEQ ID NO:8, not by reference to particular clones described by deposit number. Applicant has now altered the sequence of the nucleic acids encoding the claimed protein. This alteration constitutes the introduction of new matter. Applicant is required to cancel the new matter in the reply to this Office action.

8. Claims 173-176 and 179-181 are rejected under 35 U.S.C. 112, first paragraph as lacking adequate description and enablement for the MAGE-1 sequence of SEQ ID NO:8 as amended.

The instant claims are not directed to the two specific nucleic acid sequences of SEQ ID NOS 7

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and 8 that may have inherently been in possession at the time of filing. The instant claims are directed to the protein or amino acid sequences which these sequences encode. The instant specification as filed does not describe so as to enable production of MAGE-1 protein because the nucleic acid sequence of MAGE-1 (SEQ ID NO:8) was not properly described.

9. The following documents contain 100% matching sequences to SEQ ID NO:8.

WO 94/23031-A published 13-Oct-1994, Boon-Falleur et al. (Not prior art)  
WO92/20356-A, published 26-Nov-1992, Boon et al. (Not prior art)  
WO95/20974-A, published 10-Aug-1995. Boon-Falluer et al. (Not prior art)  
U.S. patent 5,541,104, published 30-Jul-1996, filed 01-Feb-1994. Chen et al. (Not prior art)  
Science 254:1643-1647, published 13-Dec-1991. Van der Bruggen et al. (Not prior art)

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



THOMAS M. CUNNINGHAM  
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